Meeting Notes
Clinical Advisory Panel

August 15, 2001 – 980 Ninth Street, Sacramento

Panel Members Present – Antonio Linares, M.D.; Peter J. Panzarino, M.D.; David Bergman, M.D.; John Alksne, M.D.; Edward Savage, Jr., M.D. (Herbert A. Berkoff, M.D. was absent.)

Introductions –Antonio Linares, M.D., Medical Advisor to the Director, opened the fourth meeting of the Clinical Advisory Panel.

HMO Help Center IMR Report - Alan Smith reviewed the data from experience to date from the DMHC IMR process. Charts on the numbers of applications received and processed from January through June 2001 and the outcomes of the reviews were displayed, as well as lists of the conditions and disputed treatments that were submitted to IMR.

Mr. Smith provided a brief demonstration of how summarized information about completed reviews will be made available on the Department's website.

Dr. Bergman expressed concern about the potential abuse of the information and whether a more thorough disclaimer should be provided to clarify for the consumer that the information is not a precedent that can be used by plans to deny services. It should be clear that the results of past IMRs should not be viewed as precedent by potential applicants or used by the plans as justification for denials of care.

Dr. Panzarino noted that the list of types of conditions suggested one item that should be considered for trending is not only autism but also mental health cases in general. He also indicated that pain management cases seemed to be consistently denied. Disclosing information could raise issues about patient identification in high profile cases and suggests that less information about demographics, such as age and gender, and more data on the clinical condition would be advisable.

Dr. Bergman suggested that the database should be reviewed for consistency in IMR results. Part of the review process would be from the review group since this will be something a consumer will want to know.

Public comment - Dr. Tanagawa. Information should be conveyed to persons viewing the website that there are many more cases settled and resolved at the plan level. Otherwise, persons could get the impression that IMR is the only place where enrollees can submit their concerns and issues for review.

IMR Quality Review Program Report

Program overview: Tom Gilevich, DMHC counsel, provided an outline of the systems in place to assess the efficacy and operations of the Department's overall IMR process. The Department has set up different systems to evaluate and assess the results of the program in order to obtain data, as well as to ensure contract and statutory compliance. Internally, the HMO Help system and the IMR organizations assess and track eligibility, reviewer qualification, plan compliance and the resolutions of the issues submitted for review. The HMO Help Center has established an internal audit methodology and feedback is obtained from stakeholders about the IMR process through the Center and the Department's Medical Advisor. Issues are considered and handled through an IMR Advisory Council and regular meetings with the primary contractor, with the involvement of other offices of the Department, as needed.

HMO Help Internal process. Alan Smith outlined the weekly internal audit performed at the HMO Help Center on a weekly basis, assessing the internal working of the IMR system and the timelines being considered and processing of applications, plan information and medical records, as well as the Department's actions in making sure that the reviews are processed timely and efficiently through the clerical, nursing and legal staffs.

> Public comment - Beth Cappel, Health Access. Expressed concern by consumer groups that if there's any possibility that if medical necessity is involved in the determination reached by the plan, even though if couched under contractual or coverage limitations. On the face of some denials, it may not be all that clear that there is a clinical need that is being assessed.

IMR Quality Indicator / Data Tracking Process. Sigifredo Juarez (DMHC Graduate Intern) provided an overview of the tracking and trending of concerns raised about the IMR process performed by the Medical Advisor to the Director. He outlined the data base developed for the consolidation of concerns raised about reviews to provide a system to ensure pertinent comments and complaints are brought to the appropriate levels, either the internal DMHC decision-making, through the DMHC's liaison with the contractor or into the contractor's QA system. The data will also be used to give the Panel a summary each quarter of concerns that have been raised and the actions taken, if any.

> Dr. Alksne asked about how individual enrollee complaints are handled. Alan Smith indicated there have only been three. They are immediately forwarded to the counsel to assess the nature and type of concern. The Panel and Dr. Linares discussed how any complaints from enrollees are processed and how requests for re-reviews are handled when problems are addressed by enrollees.

> Public comment - Beth Cappel. She is troubled that the Department is soliciting comments from medical directors plans and not from consumers or their physicians. Having counsel re-review the case when the consumer complains is not appropriate if that puts a check onto the IMR process. Ms. Cappel also noted that with the low number of cases so far, the Department should consider asking the persons who have used the system to gauge satisfaction with the system and results.

Alan Smith noted that action on an enrollee complaint about an IMR will depend on the concerns raised - if it involves a clinical determination made by the review, the matter would go back to CHDR; if a process or system question, the counsel responds to issues relating to the case processing or implementation. Dr. Linares stated that the system was adopted to find some way to capture the comments being made about reviews and to channel them into the proper course.

Dr. Bergman: Not sure whether there is any independent audit of the review organization and thinks it might be worthwhile to use the Clinical Advisory Panel as a check on issues to see if they are worthy of comment, at least in the interim and beginning periods. (Dr. Linares noted that the HMO Help Center is currently looking for a full-time physician position to work with the nursing staff for clinical reviews.)

Dr. Savage asked why the Department had not considered a consumer database that would work together with the information obtained from the plans? (Dr. Linares noted that is something that might be obtained but this was needed now as a functional input on the process for clinical and medical grounds. Beth Cappel noted that her suggestion was to obtain consumer inputs to add to the current information to determine whether they feel the system gave them a fair shake.)

Dr. Savage inquired about the average number of cases reviewed by the CHDR physicians. Tom Naughton (CHDR California Project Manager) and Dr. Richard Weiss (CHDR California Medical) noted that there is no real average since some reviewers are used more often due to the specialty and availability plus they prefer to use California reviewers. As far as bias one way of the other, Dr. Weiss noted that he tried to stay as blind as possible as far as whether the decision upheld or overturned the plans decision. The key is whether or not the reviewer properly assessed the literature and the facts of the case.

Public comment: Dr. Apthcart (Blue Cross of California). Noted the plan's previous voluntary IMR system where divergence of reviewer opinion was assessed. He questioned whether some cases to date were evidence-based or not. Dr. Linares noted that when there is more than one reviewer, CHDR's medical director looks at the basis for any incongruence.

Dr. Panzarino noted that consistency and variability among the reviews are important and that the Department needs to track number of reviews and the number done by the reviewers.

Dr. Alksne asked whether the 100 California reviewers work exclusively with CHDR? CHDR representatives noted that is possible since that they do not require disclosure if the reviewers are doing other review work.

Public comment: Dr. Revallo (Health Plan of the Redwoods): Noted that the format of investigational/experimental reviews should be modified. (Dr. Linares noted that this had been brought to CHDR's attention in cooperation with CHDR and the Department.)

UCSF/Health Policy Study Institute. Dr. Wade Aubry, Institute for Health Policy, U.C. San Francisco.

Dr. Aubrey outlined the interagency agreement between the Institute and DMHC to provide the Department and CAP with resources for external validation and technical support to the IMR program, including the analysis of trends and variations. In addition, the agreement contemplates assessing what additional information might be needed to further develop any issues or problems raised by IMR results. Dr. Aubrey noted the numbers of case so far doesn't allow for any definitive findings but gave examples of what may later be of interest should trends continue.

- The cancer cases sent to IMR thus far reflect some consistency in the types of reviews (medical necessity vs. investigational/experimental reviews) and the types of cancers. Whether there is a trend involved for has yet to be determined.
- The three largest volume cases – gastric bypass, IDET and autism – have been detailed regarding their overturn rates but no conclusions can be drawn about reviewer bias with the few cases so far.
- The issues and resolution of Lyme disease cases have also been identified.

Variations in medical necessity and investigational/experimental; outcome in the most commonly requested IMRs, and Lyme disease are three examples of what can be looked at, in additional to any other trends or concerns that arise from the Department or CAP reviews. Dr. Aubrey suggests that the Institute can provide a resource and external validator to the IMR quality standards.

Dr. Alksne asked whether different reviewers were used for back pain/IDET cases and suggested random audits of actual reviews. Dr. Linares noted that individual cases could be reviewed if this part of trend analysis, a review of individual records in those particular cases could be obtained. Otherwise there would not be a regular or routine examination of charts unless performed in the context of a larger focused assessment.

(Dr. Linares noted that the respiratory cancer cases with 100% experimental/ investigational. Now we are looking at how many cases would be impacted by the new clinical trial legislation.)

Dr. Bergman suggested that surveying health plans to find out the types of cases coming to them would be important since IMR cases are the tip of the iceberg of where patients have problems with their plans.

Dr. Panzarino noted that there is a sense among the Panel that an external audit should be performed on some basis, annual or at least during the first year, of the reviews being conducted. Dr. Alksne and Savage concurred.

Public comment:
Dr. Revallo. Suggests that in terms of the analysis, certain indicators such as the numbers per reviewer be assessed as well as the information used regarding empiric, evidence based medicine – that may not be a complete quality review but could at least identify variables to look at. Anecdotally, the plan has two cases where the findings didn't readily state what the findings and science on which medical necessity was based.

Beth Capell. The statute does not doesn't limit the assessment to evidence-based medicine but allows for other factors to be considered. From consumer perspective, IMR was designed to provide a remedy without having to have legislation for specific diseases or conditions.

Dr. Tanagawa: While she appreciates the arguments that not all cases can or should be dealt with solely on the bass of scientific evidence, that evidence should be addressed where it exists. (She noted there was reference to a 1999 text when there was supplemental 2000 literature.)

Dr. Bergman noted that at a previous meeting, there are resources, search engines and lists that could be utilized to check the scientific evidence available to the reviewers. He would support the Department having a conversation with CHDR to be certain that the reviewers are aware of the information.

UCD Medical Center/ Center for Health Services Research in Primary Care, U.C. Davis Medical Center**.** Dr. Ed Callahan and Valerie Olson, Research Survey Manager.

Dr. Callahan and Ms. Olson discussed the potential plans under the interagency agreement with the Department to conduct a survey and physician outreach program to assess the knowledge and access to practitioners about the IMR process and how the Department may be able to educate providers better. Establish a prototype website as a tool for obtaining information when questions arise that will allow different, interactive questions. And getting an idea of provider knowledge in a trial program in Sacramento area, perhaps using different plan organizational models. Discussed idea of garnering information through focus groups, questionnaires or web-based questions. Would like the Panel to provide input and advice on the project and what should be considered to ask the questions as well as possible and use the information over time. Discussed the types of surveys – web-based, written and focus groups that could be utilized and their respective advantages and disadvantages concerning participation and depth of information and expense. Real question is the next step for the project – contribute to epidemiology of complaints and DMHC's goal to understand the nature of complaints and helping patients and providers lodge their complaints and needs.

Dr. Panzarino asked about whether the goal of the process is to determine what the physician's experience has been or their knowledge of the process? Dr. Linares indicated that it would have several roles – the Department's role and IMR as a benefit to their patients. In addition, the physicians' demographics could be explored in their participation in managed care and whether they are in primary care or specialty.

Dr. Bergman suggests additional work on focusing the purpose and work of the project. Should broaden expertise into marketing early in addition to survey research to determine how to best reach physicians. Not just limited to providers but also consumers – how can the Department get through to consumers as well. Discussion about the other Departmental and committee actions on educational efforts and marketing knowledge and talents, including the Education and Access Subcommittee and avoid going in different directions.

Public comment.
Kathy McAffrey (California Association of Health Plans): Works with provider organizations and related organizations that might be a vehicle to get information about the website. Also have some marketing expertise that might assist in this effort.

Ellen Kaufman (Institute for Medical Quality) discussed the initial findings of her retrospective study of Friedman-Knowles concerning provider involvement. While the hope was that physicians would have helped their patients navigate their way through the process and help them understand the result, that does not appear to have happened.

Dr. Savage noted that it is not entirely clear that education is necessarily a stimulus for action since there must also show there is some advantage to getting to a different result; otherwise, it's just information for information's sake.

Public comment: Dr. Navarro. He sees more of an opportunity for web-based solutions at least making doctors aware and that we should first identify the audience where they physicians are within the MCO, educate them about the process and how they should use the process.

Dr. Alksne noted that a weakness in the current system is that appealing a denial may, in a capitated group, create almost create a conflict of interest since the group may pay for any appeal that the provider supports.

Public comment:
Cas Cassanov (Kaiser Permanente) asked whether there had been any information gathered on how frequently the treating physician supports the IMR request? Dr. Linares noted that current systems don't gather that data. The question is what the end goal is and the amount of support and advocacy of the treating physician doesn't seem to look at the larger issues. Information could be captured on the assertions that plans are reversing the treating physicians' recommendations.

Blue Shield physician: Additional variable in physician advocacy are the different physician demographics in whether physicians in fee-for-service products vs. those in HMO models.

Informational Items

Child and Adolescent Mental Health Stakeholder meeting

Dr. Linares has contacted interested partied in a planning committee meeting through teleconference – including representatives from California Psychiatric Association, CAHP and private practitioners. Consumer representative and input desired. Looking at November 2nd in Sacramento – not a meeting of the Clinical Advisory Panel but a follow up to an earlier presentation by members of the California Psychiatric Association. Recommendations thus far would include using specific sample cases as a format and to include specialized plan and medical groups. Clinical coordination and interface between behavioral and medical services to insure continuity as one focus, with the types of service available as another.

DMHC Directive for Diabetes Best Practices and SB64 Compliance

Previously discussed the implementation of SB64 that required coverage for diabetes supplies and disease education with reducing variation in implementation is focus for the Department. The adoption and existence of guidelines from national and state groups, including AMA, NCQA and JCAHO, as well as PBGH and CCHRI have already been adopted by some 15 or 20 plans since March that should be used rather than construct a duplicate.

Rather than reinvent the wheel, determined that it would be better to assemble a small panel of experts with an endorsement of best practices, with desired result a clinical bulletin from the director.

Beth Cappel recommended participation from the Diabetes Association and Western Center for Law and Poverty.

Informational Item – Clinical Trials Legislation

Tom Gilevich outlined the provisions of SB 37, a bill just signed by the governor that will require coverage for participation in cancer clinical trials. Further information and comparison with Medicare's standards will be provided at the next meeting of the Panel.

[Corrections or comments regarding these notes should be provided to Tom Gilevich, DMHC Counsel at (916) 324-9024; FAX (916) 322-3968 ; TGilevich@dmhc.ca.gov.]